

## Interview Summary

Application No.

08/739,264

Applicant(s)

Marshall et al.

Examiner

Mary K Zeman

Group Art Unit

1815



All participants (applicant, applicant's representative, PTO personnel):

(1) Mary K Zeman

(3) \_\_\_\_\_

(2) Heidi Nebel

(4) \_\_\_\_\_

Date of Interview Apr 23, 1998Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description:\_\_\_\_\_  
\_\_\_\_\_Agreement ☒ was reached. ☐ was not reached.Claim(s) discussed: 1-4, 6, 7, and 24-34

Identification of prior art discussed:

none  
\_\_\_\_\_

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Amendments to the claims which would place the application in condition for allowance were discussed (see attached).The submission of a rule 132 declaration was discussed to clarify the differing stressing conditions which result the the production of the stress release product. The agreed upon changed are reflected in the examiner's amendment.  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☒ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

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~~(c) Separating~~

removing said bacteria to form a separate product

Claim 1. A method for activating and modulating the immune system of an animal comprising:

(a) growing.....(text ok)

(b) exposing...(text ok)

(c) separating said medium and stress release product from said bacteria to form a separated product; *filtering to remove ~ Sterile preparation ~ More functional*(d) filtering said separated product through a 0.22 micron filter to obtain a filtered product; *separated*(e) filtering said ~~filtered~~ product through a filter having a 10,000 dalton molecular weight cutoff to obtain said stress release product; and

(f) administering an effective amount of said stress release product to said animal;

wherein the biological, chemical or physical stress of step (b) is selected from the group consisting of:

altering the pH of said medium,

reducing the bioavailability of nutrients of said medium,

removing nutrients from said medium,

crowding by reducing the volume of said medium,

crowding by adding additional bacteria to said medium, and

removing said bacteria from said medium by centrifugation and resuspending said bacteria in a non-nutritive isotonic solution.

*getting rid of stressors  
132 declaration  
2 osmolarity  
Avoid long list*Cancel claims 2 ~~and 3~~ (limitations incorporated into claim 1)

Claim 4 would depend from claim 1. 3

Claim 6 would be canceled. (limitations incorporated into claim 1)

Claim 7 would depend from claim 1. 7

Claims 8-23 were canceled in the response.

Claim 24. A method for modulating the immune system of an animal comprising:

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administering to said animal a product released by bacteria in response to stress wherein the stress release product is made by a method comprising: (a) growing.....

(b) exposing...

(c) separating said medium and stress release product from said bacteria to form a separated product;

(d) filtering said separated product through a 0.22 micron filter to obtain a filtered product;

(e) filtering said filtered product through a filter having a 10,000 dalton molecular weight cutoff to obtain said stress release product; and

(f) administering an effective amount of said stress release product to said animal;

wherein the biological, chemical or physical stress of step (b) is selected from the group consisting of:

altering the pH of said medium,

reducing the bioavailability of nutrients of said medium,

removing nutrients from said medium,

crowding by reducing the volume of said medium,

crowding by adding additional bacteria to said medium, and

removing said bacteria from said medium by centrifugation and resuspending said bacteria in a non-nutritive isotonic solution;

and further providing that the stress release product is administered to the animal in a delivery form selected from the group consisting of forms for parenteral delivery, gels for oral delivery, lozenges for oral delivery, nasal sprays, ear drops, vaginal creams, vaginal suppositories, and topical ointments.

Claim 25- no change.

Claim 26: change "the product" to "said stress release product" and "stress factors" to "said stress release product"

Cancel claim 27.

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Claim 28- change "the product" to "said stress release product"

Claim 29: change "factors have" to "product has"

Claim 30: change "the product" to "said stress release product"

Claim 31: change "the product" to "said stress release product" and delete "to produce higher levels.....pathogen"

Claim 32: A method of maintaining the viability of bacteria during storage and shipment comprising:

administering to said bacteria a product released by bacteria in response to stress, wherein the stress release product is made by a method comprising: (a) growing.....

(b) exposing...

(c) separating said medium and stress release product from said bacteria to form a separated product;

(d) filtering said separated product through a 0.22 micron filter to obtain a filtered product;

(e) filtering said filtered product through a filter having a 10,000 dalton molecular weight cutoff to obtain said stress release product; and

(f) administering an effective amount of said stress release product to said animal;

wherein the biological, chemical or physical stress of step (b) is selected from the group consisting of:

altering the pH of said medium,

reducing the bioavailability of nutrients of said medium,

removing nutrients from said medium,

crowding by reducing the volume of said medium,

crowding by adding additional bacteria to said medium, and

removing said bacteria from said medium by centrifugation and resuspending said bacteria in a non-nutritive isotonic solution.

Claim 33: "pneurmoniae" to "pneumoniae"

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Claim 34: A method for activating and modulating the immune system of an animal comprising:  
growing bacteria.... (text ok- except "pneurmoniae" to "pneumoniae")  
exposing said bacteria... (text ok)  
separating said medium from the bacteria to obtain a separated product;  
filtering said separated product through a 0.22 micron filter to obtain a filtered product;  
filtering said filtered product through a filter having a 10,000 dalton molecular weight cutoff to  
obtain said stress release product; and  
administering an effective amount of said stress release product to said animal;  
wherein the biological, chemical or physical stress of step (b) is selected from the group consisting  
of:  
altering the pH of said medium,  
reducing the bioavailability of nutrients of said medium,  
removing nutrients from said medium,  
crowding by reducing the volume of said medium,  
crowding by adding additional bacteria to said medium, and  
removing said bacteria from said medium by centrifugation and resuspending said bacteria in a  
non-nutritive isotonic solution.

mkz

4/15/98

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